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10/525,644	03/17/2005	Takeshi Ito	28361U	8336

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EXAMINER	
ELLIS, SUEZU Y	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,644	ITO ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terahara et al. (WO 02/38139). Hereinafter, US 2004/0028724 will be used as an English equivalent translation.

With respect to claim 1, Terahara et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and oxybutynin and/or a pharmaceutically acceptable salt thereof [0043], [0022], wherein the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group in the molecule, and a rubber polymer [0012], [0029], [0030]. Terahara et al. also discloses the acrylic polymer being 5-50% by weight and the rubber polymer being 20-40% by weight [0030], [0031]. Terahara et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4, as demonstrated in Example 1. It would have been obvious to one of ordinary skill in the

art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug [0031]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 2, the modified Terahara et al. discloses the adhesive layer comprising 2-88% acrylic polymer [0031], 20-40% by weight rubber polymer [0030], and 10-50% by weight an alicyclic saturated hydrocarbon resin-based tackifier [0033]. More specifically, Terahara et al. demonstrates in Example 1, the adhesive layer comprising 5% by weight of an acrylic polymer, 20% by weight of a rubber polymer and 38% by weight of an alicyclic saturated hydrocarbon resin-based tackifier.

With respect to claim 3, the modified Terahara et al. discloses in Example 1, the weight ratio of total content of the acrylic polymer and the rubber polymer to content of the tackifier is from 1:1 to 1:3.

With respect to claim 4, the modified Terahara et al. discloses the acrylic polymer is a copolymer of polyarylate including butyl acrylate [0012], [0031].

With respect to claims 5 and 6, the modified Terahara et al. discloses the rubber polymer is at least one kind selected from styrene-isoprene-styrene block copolymer [0029].

With respect to claim 8, the modified Terahara et al. discloses the adhesive layer is compounded with oxybutynin hydrochloride [0022].

With respect to claims 9 and 10, the modified Terahara et al. discloses the adhesive agent further comprises an organic acid (carboxylic acid) that is citric acid or acetic acid [0017], [0024], [0025].

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232).

With respect to claim 1, Chono et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent (organic acid) and oxybutynin and/or a pharmaceutically acceptable salt thereof [0014], [0015] wherein the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group in the molecule, and a rubber polymer [0030]. Chono et al. also discloses the acrylic polymer being 10-98% by weight and the rubber polymer being 15-50% by weight [0031]. Chono et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 4-7, the modified Chono et al. discloses the acrylic polymer is copolymer of 2-ethylhexyl acrylate and vinyl acetate monomers, and the rubber polymer is styrene-isoprene-styrene block copolymer [0030], [0031].

With respect to claim 8, the modified Chono et al. discloses the adhesive layer is compounded with oxybutynin hydrochloride [0015].

With respect to claims 9 and 10, the modified Chono et al. discloses the adhesive agent comprises an organic acid (acetic acid) [0017].

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8 and 13 of copending

Application No. 10/469,612 (amendment filed on 10/4/07) in view of Terahara et al. WO 02/38139 (US 2004/0028724 is used as an English equivalent translation).

This is a provisional obviousness-type double patenting rejection.

With respect to claim 1 of the current application, claims 1, 8 and 13 of Application No. 10/469,612 (amended claims filed 10/4/07) discloses:

(claim 1) **A patch comprising a support (functionally equivalent to a backing layer), and an adhesive layer** laid on the support and containing an adhesive base **(adhesive agent)** and a drug, wherein said adhesive base contains an **acrylic polymer substantially having no carboxyl group and no hydroxyl group in molecules thereof**, wherein said polymer is at least one selected from the group consisting of: a 2-ethylhexyl acrylate N-vinyl-2-pyrrolidone 1,6-hexane glycol dimethacrylate copolymer; an aminoalkylmethacrylate copolymer E; and a 2-ethylhexyl acrylate vinyl copolymer; **and a rubber-based polymer**.

(claim 8) wherein **said drug is at least one selected from** the group consisting of pergolide, pharmacologically acceptable salts of pergolide, **oxybutynin, and pharmacologically acceptable salts of oxybutynin.**

(claim 13) **wherein said drug is selected from the group consisting of oxybutynin and pharmaceutically acceptable salts of oxybutynin.**

Claims 1, 8 and 13 of Application No. 10/469,612 fail to expressly disclose the weight ratio of content of the acrylic polymer to content of the rubber polymer being from 1:4 to 1:19. Terahara et al. discloses a patch comprising oxybutynin having an adhesive comprising of an acrylic polymer that is substantially free of both carboxyl and

hydroxyl groups and a rubber polymer having a range of weight ratios, wherein the weight ratio can be 1:4 [0030], [0031]. It would have been obvious to one of ordinary skill in the art to modify the weight ratios in order to optimize the formation of the adhesive layer and sufficient skin permeability of the drug [0031]. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed February 14, 2008 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1-6 and 8-10 in view of Terahara et al., applicant argues that Terahara et al. does not disclose the combination of components of oxybutynin, a rubber polymer and an acrylic polymer substantially free of both hydroxyl and carboxyl groups in the molecule. However, applicant does acknowledge Terahara et al. teaches the use of oxybutynin hydrochloride in para. [0054], but argues "an acrylic polymer substantially free of carboxyl and hydroxyl groups in the molecule and rubber polymer" is not disclosed. Examiner respectfully disagrees. Para. [0029]-[0031] teach the use of the combination of acrylic and rubber polymers. These paragraphs also suggest the use of the same polymers in the specification and claims of the instant application (see claims 4-6). Para. [0029] and [0031] suggest the use of styrene-isoprene-styrene block copolymer as the rubber polymer, and butyl acrylate as

the acrylic polymer, respectively. Therefore, the polymers are considered to have the same properties as that of the instant application (being substantially free of carboxyl and hydroxyl groups). While Terahara et al. does not provide an example having all the claimed elements, examiner notes that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments, and patents are relevant as prior art for all they contain (see MPEP 2123).

Applicant further argues that there is a lack of motivation to combine the known elements. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Terahara et al. teaches in para. [0029] and [0031], ranges of the rubber polymer and ranges of the acrylic polymer that overlaps the claimed ranges to provide good skin permeability. Therefore, one of ordinary skill in the art would expect to try various ratios in order to find the range(s) that provide optimal skin permeability of the drug. Further, the examiner notes that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Applicant further argues unexpected results of the claimed matrix and directs the examiner to the Tables presented in the instant specification. However, examiner respectfully disagrees. Since Terahara et al. teaches overlapping ranges and the ranges are in consideration of the formation of the adhesive layer and sufficient skin permeability of the drug [0029], [0031], one of ordinary skill in the art would expect to try different ratios/ranges in order to optimize the skin permeability of the drug. Further, while the tables demonstrate a difference in the skin permeability rate, this appears to be a mere difference in degree. In addition, the showings in the examples are not commensurate in scope with the claims. Claim 1 recites "the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group and a rubber". The showings provide only one acrylic polymer and one rubber. In order for the showings to be commensurate in scope with the claim, the showings need to demonstrate various types of acrylic polymer and rubbers, not just one type of each. Further, the showing demonstrates the inclusion of excipients, which are not in the claim. The showings would need to demonstrate the adhesive with the rubber and the acrylic polymers alone, without the excipients to demonstrate the excipients have no bearing on the skin permeability results. Thus, applicant's arguments are not persuasive.

Therefore, the rejection of claims 1-6 and 8-10 over Terahara et al. is maintained.

With respect to the rejection of claims 1 and 4-10 in view of Chono et al., applicant argues unexpected results of the claimed matrix and directs the examiner to

the Tables presented in the instant specification. Applicant further argues Chono et al. does not provide examples for the combination of components of oxybutynin, a rubber polymer and an acrylic polymer substantially free of both hydroxyl and carboxyl groups in the molecule. While Chono et al. does not provide an example having all the claimed elements, examiner notes that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments, and patents are relevant as prior art for all they contain (see MPEP 2123). Further, examiner directs applicant to paragraphs [0030] and [0031]. Para. [0030] recites the same polymers as applicant's claims 4-7, and para. [0031] recites the combination of the rubber and acrylic polymers, and provide for ranges that overlap applicant's claimed ranges.

Chono et al. teaches ranges of the rubber polymer and ranges of the acrylic polymer that overlaps the claimed ranges in para. [0031]. Therefore, one of ordinary skill in the art would expect to try various ratios in order to find the range(s) that provide optimal skin permeability of the drug. Further, the examiner notes that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Further, while the tables demonstrate a difference in the skin permeability rate, this appears to be a mere difference in degree. In addition, the showings in the examples are not commensurate in scope with the claims. Claim 1 recites "the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group and a rubber". The showings provide only one acrylic polymer and

one rubber. In order for the showings to be commensurate in scope with the claim, the showings need to demonstrate various types of acrylic polymer and rubbers, not just one type of each. Further, the showing demonstrates the inclusion of excipients, which are not in the claim. The showings would need to demonstrate the adhesive with the rubber and the acrylic polymers alone, without the excipients to demonstrate the excipients have no bearing on the skin permeability results. Thus, applicant's arguments are not persuasive.

Therefore, the rejection of claims 1 and 4-10 over Chono et al. is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615